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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,006	09/10/2001	Felix Montero Julian	JULIAN-1	1262
1444	7590	05/05/2004	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			LAM, ANN Y	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,006

Applicant(s)

MONTERO JULIAN ET AL.

Examiner

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☒ Claim(s) 4-10, 15 and 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

In response to Applicant's argument regarding the restriction requirement, Examiner hereby withdraws the restriction requirement.

Claim Objections

Claims 4-10, 15 and 16 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-16 do not include "comprising", "consisting of", "consisting essentially of", or the equivalents of those terms.

Claims 1-10 need to positively recite the step of detection or quantification.

Claim 16, since it claims a process, needs to positively claim the step of providing a sample, contacting the sample with the antibody claimed, and detection or quantification step.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 11 is rejected under 35 U.S.C. 102(e) as being anticipated by Koike et al., 6,018,032.

Koike et al. disclose an anti-IL-5R antibody characterized by: the absence of interference with the fixing of IL-5 to its receptor (see column 1, lines 64-67; column 5, lines 8-21), the absence of interference with IgE, the absence of interference with cell activation of eosinophils or basophils, the absence of inhibition of the biological activity of IL-5 (see column 75, lines 1-5, which discloses monoclonal antibodies that bind to human IL-5 receptor alpha chain, as opposed to the monoclonal antibodies in column 75, lines 6-10, which can bind to human IL-5 receptor alpha chain and which can inhibit the biological activity of human IL-5.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson et al., 5,776,709, in view of Koike et al., 6,018,032.

Jackson et al. discloses the invention substantially as claimed. Jackson discloses a kit for the analysis of leukocytes, the kit comprising a mixture of antibody markers for lymphocytes, monocytes and neutrophils, conjugated to a second fluorochrome (see column 4, lines 64-67, and column 10, lines 67), antibodies directed against activation markers and conjugated to a third fluorochrome (see column 11, lines 2-4.) As to claim 14, the anti-leukocyte antibody conjugated to the third fluorochrome is the marker substrate for the oxidative activity of eosinophils.

Jackson et al. also discloses using an anti-leukocyte antibody conjugated to a first fluorochrome. However, Jackson et al. does not specify that the anti-leukocyte antibody is anti-IL-5R antibody.

Koike et al. discloses that anti-IL-5R antibody can be used for the detection of eosinophils (see column 5, lines 9-18.) Since Jackson et al. teaches that the antibodies may be polyclonal or monoclonal and may be any antibody capable of binding to the cellular characteristic of interest (see column 7, lines 60-63 and column 8, lines 12-14),

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it would have been obvious to provide anti-IL-5R antibody, as taught by Koike et al., as the anti-leukocyte that is conjugated to the first fluorochrome in the Jackson et al. kit.

Allowable Subject Matter

Claim 1 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

Claims 2 and 3 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: a method for the detection or quantification of eosinophils and basophils comprising the steps of bringing a sample into contact with an IL-5 anti-receptor (alpha chain) monoclonal antibody was not found in the prior art search.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ames, Jr. et al., 5,693,323, disclose a method of detecting the presence of IL-5/antibody to indicate excess eosinophils is disclosed. Schleimer et al., 6,599,914, (filed April 24, 2001) discloses detection of basophils using IL-5. Gerard et al., 6,537,764, discloses antibodies to detect expression of receptors on eosinophils and basophils.

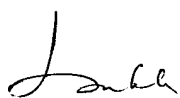
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703)305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

A.L. 


LONG V. LE
SUPERVISORY PATENT EXAMINER
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02/09/04